Anti-CCP

Anti-Cyclic Peptide Containing Citrulline Antibody Test Kit
(Rate Scattering Turbidimetric Method)

Instructions for Use

Version: A/8

REF HP-Anti-CCP-25

Manufacturer

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Product Name

General Name:Anti-Cyclic Peptide Containing Citrulline
Antibody Test Kit（Rate Scattering Turbidimetric Method）

Specification

Package Specification
25 Tests/ Kit.

Intended Use

This product is used to determine the content of anti-cyclic
peptide containing citrulline antibody (Anti-CCP) in human
serum.

Anti-cyclic peptide antibody is a polypeptide fragment of annu-
lar polyfilament protein. It is a kind of autoantibody based on
IgG, and can be used in the auxiliary diagnosis of rheumatoid
arthritis (RA).

Test Principle

The cyclic citrulline peptide antigen is coated on the latex
surface. The anti-cyclic peptide containing citrulline antibody
in the sample and the antibody become to immune complexes
by Latex agglutination reaction. The immune complexes will
produce the phenomenon of light scattering which is propor-
tional to the intensity of scattered light and samples of
Anti-CCP levels. Using specific protein analyzer to measure the
intensity of scattered light, the concentration of Anti-CCP is
determined by comparing the turbidity of samples to the stan-
dard concentration.

Component

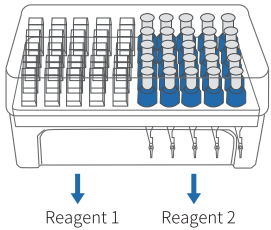The Anti-CCP test kit consists of two reagents R1 and R2, as
shown on Figure 1.

Figure 1

Reagent 1   Reagent 2

Name	Content	Quantity
Reagent 1 (R1)	Phosphate buffer(pH 6.5)	0.1mol/L
	Sodium azide	0.1%
	Polyethylene glycol 6000	3.5%
Reagent 2 (R2)	Phosphate buffer(pH 8.0)	0.1mol/L
	Cyclic citrullin peptide antigen with latex	4.3mL/L
IC card (optional)	/	1

Do not mix different batches of reagents.

Storage&stability

Store the test kit at 2°C-8°C until the expiration date indicated
on the label. The test kit is stable for one year when unopened.
Use up the test kit within one month after opening the pack-
age.
Do not freeze the test kit.
Do not mix different lots of the test kit.

Special Instrument Requirements

HP-083/4-I POCT Immunoassay System,
HP-083/4-II POCT Immunoassay System,
HP-AFS/1 Automatic Immunoassay System,
HP-AFS/3 Automatic Immunoassay System.

Specimen type

Serum, avoid hemolysis. Fasting blood collection and separa-
tion of serum as soon as possible. The sampl e store at 2-8°C
for 3 days, -20°C for 1 month. Avoid repeated freezing. Before
test, ensure fully mixed.

## Procedures

HP-083/4-I&HP-083/4-II POCT Immunoassay System

Note:

- Please read user manual of HP-083/4-I and HP-083/4-II
  before use.
- The analyzer will finish self check after start-up.
- Insert the IC card of Anti-CCP test kit to let analyzer read the
  parameter.
- The analyzer calibration can be done with app. It is recom-
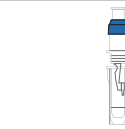 mended that analyzer calibration should be done for each
  new lot of test kit.

Step 1 Sample Preparation
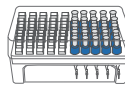
1a Allow the test kit back to room temperature for 30 minutes before use.
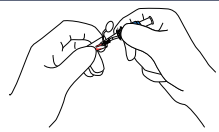
1b Use the R2 with quantitative capillary to collect sample.

1c Insert the R2 into R1.

Note:

- The parameter is built in the IC card.
- Please insert the corresponding IC card into analyzer to let
  the analyzer read the parameter before each assay test.
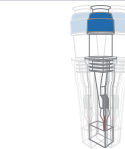- The capillary of the R2 should be fully filled.

Step 2 Testing

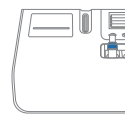**2a** Hold the narrow side of R1 and shake from left to right for 12 times to let the sample completely mix with R1.

Note: Do not hold the wide sides of R1.

2b Press the piston on R2.

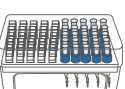**2c** Hold the narrow sides of R1 and shake for 3-5 seconds to let R1 and R2 mix well.

2d Insert the R1 into test channel of HP-083/4-II and the analyz-er will finish the test and print out results automatically.

HP-AFS/1&HP-AFS/3 Automatic Immunoassay System

Note:

- Please read user manual of HP-AFS/1 and HP-AFS/3 before
  use.
- The analyzer will finish the self check after start-up.
- It is recommend to do analyzer calibration monthly and for
  each new lot of test kit.

Step 1 Sample Preparation

3a Allow the test kit back to room temperature for 30 minutes before use.

3b Use the R2 with quantitative capillary to collect sample.

3c Insert the R2 into R1.
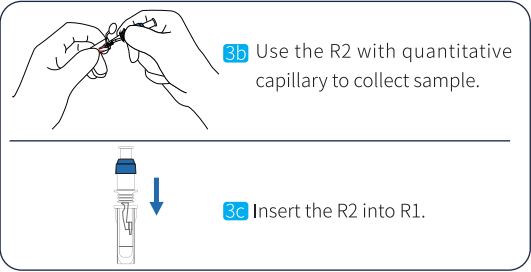
Note:

- Please update the standard curve with the barcode on the R1 cuvette if a new lot test kit is to be used.
- The capillary of the R2 should be fully filled.

Step 2 Testing

4a Insert the R1 into test channel of analyzer.

4b The analyzer will mix the sample from R2 capillary with R1 automatically.

4c The analyzer will mix the R2 and R1 automatically.

4d The analyzer will test and print the results automatically.

Calibration

The calibration values for the different lots of the kits are stored on the calibration IC card or the two-dimensional code on the cuvette. Before test the new lot of kits, read the calibration card parameters first. Or the instrument automatically scan the two-dimensional code on the cup to obtain the corresponding calibration curve during testing.

Quality control

3- level calibration system guarantee the results' reliability for each lot of test kits, including the instrument calibration, remote reagent calibration and the third party calibration.

The third party calibration applicable for:

1. The daily indoor quality control test.

2. New lots of reagent.

3. New operator training.

4. The results can not match the clinical symptoms.

5. The first use of the reagent.

If still can not be calibrated, contact the manufacture for further technical support.

Reference Value

＜45U/mL. Recommended that each laboratory establish its own reference range.

Interpretation

The test results≥45U/mL indicate that patients have rheumatoid arthritis, it is recommended to conduct further examinations.

The result only for clinical reference, comprehensive consideration should be combined with the clinical management of patients with symptoms / signs, medical history, other laboratory tests and treatment response.

All laboratory tests depend on random errors. If the test results are in doubt, or if they do not match the clinical symptoms, re-test the sample or confirm the results with other methods.

Limitations

Hemoglobin>5g/L, triglyceride>5mmol/L, bilirubin＞97μmol/L will affect the test result.

Performance Characteristics

1. Linearity range: 5U/mL ～ 400U/mL.

2. Precision

   Test the control material by Anti-Cyclic Peptide Containing Citrulline Antibody Test Kit 2 times per day for 20 days (n=80)

The data as below:

a.

HP-083/4-II POCT Immunoassay System					
Sample	Mean U/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	22.67	1.38	6.1	1.41	6.2
Control 3	72.63	2.91	4.0	2.98	4.1

b.

HP-AFS/3 Automatic Immunoassay System					
Sample	Mean U/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	22.68	1.41	6.2	1.43	6.3
Control 3	72.71	3.05	4.2	3.20	4.4

c.

HP-AFS/1 Automatic Immunoassay System					
Sample	Mean U/mL	Within-Run		Between-Run	
		S.D.	%C.V.	S.D.	%C.V.
Control 1	22.58	1.35	6.0	1.42	6.3
Control 3	71.49	4.00	5.6	4.29	6.0

3.Methodology comparison

Compared to Anti-CCP LIA(x) by test the same serum sample, the relative data as below:

HP-AFS/3 Automatic Immunoassay System				
Site No.	Sample Type	No.of Assays	Regression Line	Coefficient correlation
1	Serum	50	Y= 1.04X+0.10	0.97

The concentration of sample is about 5U/mL ～ 400U/mL.

SYMBOLS USED ON LABELS

Symbol	Usage	Symbol	Usage
⧗	Use-By date	❄	Do not freeze
LOT	Batch code	☣	Biological risks
▟	Manufacturer	⊘	Do Not Reuse
⌇	Temperature Limit		
∑∇	Contains sufficient for <n> tests		
⊗	Do not use if package is damaged		
📖	Consult Instructions for use		
☀	Keep Away from Sunlight		
IVD	In Vitro Diagnostic Medical device		
EC REP	Authorized Representative in the European Community		

References

1、Sehellekens GA, Visser H, De Jong BA, et al. The diagnostic properties of rheumatoid arthritis antibodies recognizing a cyclic citrullonated peptide. Arthritis Rheum, 2000, 43: 155-163.

2、Liao KP, Batra KL, Chibnik L, et al. Anti-CCP revised criteria for the classification of rheumatoid arthritis. Ann Rheum Dis, 2008, 30.

3、Yamane T, Hashiramoto A, Tanaka Y, et al. Easy and Accurate Diagnosis of Rheumatoid Arthritis Using Anti-Cyclic Citrullinated Peptide 2 Antibody, Swollen Joint Count, and C-Reactive Protein/Rheumatoid Factor. J Rheumatol, 2008, 35(3): 414-420.

Approval Date&Revision Date

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Revision Date：Feb 1,2019
Revision Date：Apr 1,2019
Revision Date：Jan 1, 2021
Revision Date：Apr 1, 2021
Revision Date：Jan 1, 2023
Revision Date：Dec 22,2023

CE IVD

尺寸:24*25cm展开尺寸,横向三折页再垂直方向两次对折